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EXAMINER	
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ART UNIT	**PAPER NUMBER**
2624	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/598,764	WEISS ET AL.	
	Examiner	Art Unit	
	TAHMINA ANSARI	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19-25 and 46-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-17,19-25 and 46-50* is/are allowed.

6)☒ Claim(s) *51-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/25/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This is in response to the applicant's reply filed May 21, 2010. In the applicant's reply; claims 1, 13, 19-21, and 24 were amended, claims 18 and 26-44 were cancelled, and claims 45-56 were added. Claims 1-17, 19-25, and 45-56 are pending in this application.

Examiner's Responses to Applicant's Remark

2. Applicants' amendments filed on May 21, 2010 have been fully considered. The amendments overcome the following rejections set forth in the office action mailed on January 28, 2010.

a. Applicant's amendments overcome the objections of claims 1 and 13, and the objection is hereby withdrawn.

b. Applicant's cancellation of claims 34 and 43 renders the objection of these claims as moot, and the objection is hereby withdrawn.

Specification

3. The disclosure is objected to because of the following informalities.

- Figure 16B is not properly described in the "Brief Description of the Figures".
- Page 12 line 28, the use of element "block 46" with respect to Figure 1, appears to be a typo, as Figure 1 does not have any element with this label. For the purposes of the examination, this is being examined as "block 45".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 51 and 53-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. Claim 51 lines 5-18, the claimed limitations are directed towards "(b) a program stored in the memory and configured to create a medical image from the CT image data set using: (i) a first reconstruction algorithm, wherein the first reconstruction algorithm is optimized for display of the first type of tissue; and (ii) a second reconstruction algorithm, wherein the second reconstruction algorith is optimized for display of the second type of tissue; (c) a processor in communication with the memory to perform the program; and (d) a display in communication with the processor, wherein the program is configured to cause a composite medical image comprising a portion corresponding to the first type of tissue and a portion corresponding to the second type of tissue to be presented on the display, wherein the portion of the composite medical image

corresponding to the first type of tissue is created using the first reconstruction algorithm, wherein the portion of the composite medical image corresponding to the second type of tissue is created using the second reconstruction algorithm" but these limitations are not defined in the specification, and are new matter.

c. Claim 53 lines 1-4, the claimed limitations are directed towards "acquiring a plurality of medical diagnostic images of a neuro-axis of a patient with *rapid sagittal MRI opposed-phase GRE sequences having a total acquisition time of less than one minute,* wherein the parameters of the sequences are selected so that discs have the highest signal intensity amongst spinal structures" but these limitations are not defined in the specification, and are new matter.

d. Claim 54 lines 1-3, the claimed limitations are directed towards "A method comprising: *acquiring a plurality of medical diagnostic images of a neuro-axis of a patient with multi-gradient and spin echo MRI sequencing*", but these limitations are not defined in the specification, and are new matter.

e. Claim 55 lines 7-13, lines 12-14 the claimed limitations are directed towards "wherein the *at least one parameter comprises a parameter map taken from the list consisting of: (i) aT2 map; (ii) a T2* map; (iii) a T2' map; (iv) a fat map; and (v) a water map*", and towards "(iii) *using the identification of the plurality of spinal structures, and at least one parameter map derived from the plurality of medical diagnostic images, automatically assess the patient for at least one neuro-axis pathology*", but these limitations are not defined in the specification, and are new matter.

f. Claim 56 lines 1-3, the claimed limitations are directed towards “A method comprising: (*a) acquiring a medical diagnostic image of a neuro-axis of a patient with multi-echo MRI sequencing*”, but these limitations are not defined in the specification, and are new matter.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 51, 53 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 51 line 10 the use of “algorith" appears to be a typo and leads to indefiniteness. For the purposes of examination, this will be examined as “algorithm”.
- Claim 51 lines 5-18 the limitation ““wherein the portion of the composite medical image corresponding to the first type of tissue is created using the first reconstruction algorithm, wherein the portion of the composite medical image corresponding to the second type of tissue is created using the second reconstruction algorithm” leads to indefiniteness, as it is unclear with the usage of two "wherein" clauses.
- Claim 53 lines 2-4, the use of “rapid sagittal MRI opposed-phase GRE sequences” is unclear and leads to indefiniteness.

- Claim 55 lines 9-11, the use of "(i) a T2 map; (ii) a T2* map; (iii) a $T2^{\dagger}$ map" leads to indefiniteness, as the terminology for these maps is not defined in the claim language.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claim 51 is rejected under 35 U.S.C. 102(e) as being anticipated by Armato III et al. (US PGPub US 2003/0086599 A1, hereby referred to as “Armato”).

Consider Claim 51.

Armato teaches:

-; “An apparatus comprising: (a) a memory configured to receive a CT image data set, the CT image data set corresponding to a portion of a patient's body comprising a first type of tissue and a second type of tissue” **(Armato: abstract, [0030]-[0036], [0069]-[0077], [0127]-[0129], Figure 1-3, Figure 11-12)**;

-; “(b) a program stored in the memory and configured to create a medical image from the CT image data set using" **(Armato: [0069]-[0077], [0127]-[0129], Figure 11-12)**:

-; “(i) a first reconstruction algorithm, wherein the first reconstruction algorithm is optimized for display of the first type of tissue" **(Armato: [0069]-[0077], [0084]-[0092], Figure 3A-9B; a chest wall is delineated through the segmentation of a rib region, wherein the ribs are reconstructed using a region-growing algorithm)**;

-; “and (ii) a second reconstruction algorithm, wherein the second reconstruction algorith is optimized for display of the second type of tissue" **(Armato: [0069]-[0077], [0078]-[0083], Figure 2A-2B; a second reconstruction algorithm is optimized for segmenting the lung region using contour-based segmentation and thresholding)**;

-; “(c) a processor in communication with the memory to perform the program" **(Armato: [0069]-[0077], [0127]-[0129], Figure 11-12)**;

-; “and (d) a display in communication with the processor, wherein the program is configured to cause a composite medical image comprising a portion corresponding to the first type of tissue and a portion corresponding to the second type of tissue to be presented on the display" (**Armato: [0069]-[0077], [0127]-[0129], Figure 11-12)**,

-; “wherein the portion of the composite medical image corresponding to the first type of tissue is created using the first reconstruction algorithm,

wherein the portion of the composite medical image corresponding to the second type of tissue is created using the second reconstruction algorithm" **(Armato: [0042], [0069]-[0077]; the ribs, chest wall delineation, and the lung segmentation are all displayed on a graphical user interface, wherein the ribs are reconstructed through region growing, while the lung region is segmented using contour-based segmentation and thresholding)**.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tobin (US Patent 5,020,088), in view of Tannenbaum et al. (US Patent 5,593,381, hereby referred to as “Tannenbaum”), in view of Bitter et al. (US PGPub US 2005/0228250 A1 hereby referred to as “Bitter”).

Consider Claim 52.

Tobin teaches:

-; “A method comprising: (a) applying a skin surface marking system to an external surface of a portion of a patient's body selected to be imaged, wherein the system comprises a localizer comprising” **(Tobin: column 3 lines 11-20, lines 24-68, column 4 lines 1-54,)**

-; “(i) a grid; and” **(Tobin: column 4 lines 1-54)**

-; “(b) imaging the portion of the patient's body and the localizer to obtain a medical diagnostic image” **(Tobin: column 4 lines 17-54)**:

-; " (d) correlating the determined location in the medical diagnostic image with a location in the patient's body based at least in part on visual observation of the grid from the localizer which had been applied to the external surface of the portion of the patient's body" **(Tobin: column 3 lines 67-68, column 4 lines 1-42)**.

Tobin does not teach:

-; “(ii) a slice indicator positioned at a 45 degree angle relative to the grid”;

-; “wherein the medical diagnostic image comprises a cross section from the set of cross sections consisting of (i) an axial cross section”; and

-; " (ii) a sagittal cross section";

-; " (c) determining a location comprising a unique axial location and a unique sagittal location in the medical diagnostic image"; and

Tannenbaum teaches:

-; “A method comprising: (a) applying a skin surface marking system to an external surface of a portion of a patient's body, wherein the system

comprises a localizer comprising" **(Tannenbaum: column 1 lines 65-67, column 2 lines 1-45, column 3 lines 1-46, column 5 lines 20-66, Figures 1-3)**

-; "(i) a grid; and" **(Tannenbaum: column 3 lines 1-46, column 5 lines 20-66, Figures 1-3applicator is a form of a grid)**

-; "(ii) a slice indicator positioned at a 45 degree angle relative to the grid;" **(Tannenbaum: column 3 lines 1-46, column 5 lines 20-66, Figures 1-3; one recommended method uses a 45 degree angle)**;

-; " (d) correlating the location in the patient's body based at least in part on visual observation of the grid from the localizer which had been applied to the external surface of the portion of the patient's body" **(Tannenbaum: column 3 lines 1-46, column 5 lines 20-66, Figures 1-3; one recommended method uses a 45 degree angle)**.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Tobin with the teachings of Tannenbaum because they are both directed towards methods and systems for external localization of medical-related features. Tobin teaches a "base" method and system for external localization using a reference grid for a particular target region **(Tobin: abstract)**. Tannenbaum teaches a "comparable" method and system for external localization at a target skin region to provide therapeutic relief. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Tobin with the teachings of

Tannenbaum, in order to further refine the diagnostic capability to incorporate therapeutic practices, yielding predictable results. One of ordinary skill in the art, at the time of the invention, would have been motivated to combine the teachings of Tobin with the teachings of Tannenbaum in order to provide an advantageous method and system for diagnostic and therapeutic imaging that allows for an applicator to be applied “against the skin under fluids containing medical ingredients using various applicator shapes for different applications" **(Tannenbaum: column 3 lines 43-45)**.

The combination of Tobin and Tannenbaum does not teach:

-; “wherein the medical diagnostic image comprises a cross section from the set of cross sections consisting of (i) an axial cross section”;

-; "and (ii) a sagittal cross section";

-; " (c) determining a location comprising a unique axial location and a unique sagittal location in the medical diagnostic image";

-; " and (d) correlating the determined location in the medical diagnostic image with a location in the patient's body based at least in part on visual observation of the grid from the localizer which had been applied to the external surface of the portion of the patient's body".

Bitter teaches:

-; “wherein the medical diagnostic image comprises a cross section from the set of cross sections consisting of (i) an axial cross section” **(Bitter: [0030]-[0035], [0093], Figures 6a-j)**;

-; "and (ii) a sagittal cross section"**(Bitter: [0030]-[0035], [0093], Figures 6a-j)**;

-; "(c) determining a location comprising a unique axial location and a unique sagittal location in the medical diagnostic image" **(Bitter: [0030]-[0035], [0093]-[0097], Figures 6a-j, 7)**;

-; " and (d) correlating the determined location in the medical diagnostic image with a location in the patient's body based at least in part on visual observation of the grid from the localizer which had been applied to the external surface of the portion of the patient's body" **(Bitter: [0030]-[0035], [0093]-[0097], Figures 6a-j, 7)**.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination of Tobin and Tannenbaum with the teachings of Bitter because they are both directed towards methods and systems for visualization of medical-related features through image analysis. The combination of Tobin and Tannenbaum teach a “base” method and system for external localization of a target skin using a reference grid for a particular target region **(Tobin: abstract; Tannenbaum: abstract)**. Bitter teaches a method and system for visualization and navigation of medical imaging data **(Bitter: abstract)**. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination of Tobin and Tannenbaum with the teachings of Bitter, in order to further refine the methodology used for medical imaging visualization, yielding predictable results. One of ordinary skill in the art,

at the time of the invention, would have been motivated to modify the combination of Tobin and Tannenbaum with the teachings of Bitter in order to provide an advantageous method and system for diagnostic and therapeutic imaging that allows for an “cross-correlation of the associated views" in two and three-dimensional medical imaging visualization **(Bitter: [0003], [0009])**.

Allowable Subject Matter

12. Claims 1-17, 19-25, and 45-50 are allowed.

a. Claims 1-17, and 19-25 are not rejected because the prior art fails to teach the method of Claim 1, which specifically comprises the following features in combination with other recited limitations:

-;“An apparatus comprising”:

-; “(a) ***a memory configured to receive a medical diagnostic image representing a ~~neuro axis~~ neuro-axis of a patient***”;

-; (b) “***a program*** stored in the memory and operatively ***configured to detect and label a plurality of spinal structures in said medical diagnostic image using an iterative process***”;

-; (c) “a processor in communication with the memory to perform the program”

-; "wherein ***the program is further operatively configured to automatically generate a prescription using said labeling of the plurality of spinal structures***".

As these limitations are recited in independent claim 1, and claims 2-17, and 19-25 are dependent therefrom, they carry forth these limitations, and are also allowable subject matter.

b. Claims 45-50 are not rejected because the prior art fails to teach the method of Claim 45, which specifically comprises the following features in combination with other recited limitations:

-; An apparatus comprising: (a) a memory configured to receive a plurality of medical diagnostic images of a patient's neuro-axis;

-; (b) a program stored in the memory and operatively configured to:

-; (i) generate a composite midline sagittal image volume of the neuro-axis by combining two or more medical diagnostic images from the plurality of medical diagnostic images, wherein the generated composite midline sagittal image volume includes at least a portion of all interspaces and vertebrae between the patient's axis (C-2 vertebra) and sacrum; and,

-; (ii) identify a plurality of spinal structures in the composite midline sagittal image volume by iteratively searching for a predefined search number of spinal structures between the patient's axis (C-2

vertebra) and sacrum, wherein the spinal structures are taken from the set of spinal structures consisting of:

(1) intervertebral discs; and

(2) vertebrae;

-; and wherein, if the spinal structures are vertebrae, the predefined search number is 22, otherwise, if the spinal structures are intervertebral discs, the predefined search number is 23; and

-; (iii) determine if a set of predefined criteria are met and, if so, allowing the predefined search number to vary by one;

-; (c) a processor in communication with the memory to perform the program.

As these limitations are recited in independent claim 45, and claims 46-50 are dependent on claim 45, they carry forth these limitations, and are also allowable subject matter.

Some closely related prior art references are listed previously: Hipp et al. (US PGPub US 2003/0086596 A1, hereby referred to as "Hipp"), in view of Long et al. ("Landmarking and feature localization in spine x-rays", *J. Electron. Imaging,* Volume 10, Issue 4, pages 939-956, October 2001, hereby referred to as "Long"), and the references cited in form PTO-1449. None of the references teaches the *method* recited in claim 1, nor the *apparatus* recited in claim 45. Especially, Hipp is the most relevant reference. Hipp teaches a method and system to detect a plurality of spinal structures in

medical diagnostic images, but does not teach labeling the spinal structures and automatically generating a prescription using said labeling of the plurality of spinal structures. Likewise, Long teaches a method for landmarking and feature identification in spinal x-rays using labeling, and was used in combination with Hipp in previous office actions. However, neither reference teach automatically generating a prescription using said labeling of the plurality of spinal structures, as claimed in claim 1, in combination with other recited limitations. Neither Hipp nor Long, nor any of the prior art references teach the following limitations as claimed by claim 45, in combination with other recited limitations:

> -; “(i) generate a composite midline sagittal image volume of the neuro-axis by combining two or more medical diagnostic images from the plurality of medical diagnostic images, wherein the generated composite midline sagittal image volume includes at least a portion of all interspaces and vertebrae between the patient's axis (C-2 vertebra) and sacrum; and,
>
> -; (ii) identify a plurality of spinal structures in the composite midline sagittal image volume by iteratively searching for a predefined search number of spinal structures between the patient's axis (C-2 vertebra) and sacrum, wherein the spinal structures are taken from the set of spinal structures consisting of:
>
> (1) intervertebral discs; and
>
> (2) vertebrae;

-; and wherein, if the spinal structures are vertebrae, the predefined search number is 22, otherwise, if the spinal structures are intervertebral discs, the predefined search number is 23; and

-; (iii) determine if a set of predefined criteria are met and, if so, allowing the predefined search number to vary by one;

-; (c) a processor in communication with the memory to perform the program.

For these reasons, the prior art thereby does not teach the recited limitations alone or in combination.

13. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Feinberg; David A. et al., US 5270654 A, Ultra-fast multi-section MRI using gradient and spin echo (grase) imaging.

Hardy; Tyrone L. et al., US 6240308 B1, Method and apparatus for archiving and displaying anatomico-physiological data in a normalized whole brain mapping and imaging system.

Tu; Hosheng et al., US 5971968 A, Catheter probe having contrast media delivery means.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAHMINA ANSARI whose telephone number is

(571)270-3379. The examiner can normally be reached on Monday through Thursday, 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BHAVESH MEHTA can be reached on 571-272-7453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew W Johns/
Primary Examiner, Art Unit 2624

2624

/TA/

August 6, 2010